



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,604	06/26/2002	Alex Bollen	B45168	2758

20462 7590 11/03/2003

SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER

FIELD, TAMMY K

ART UNIT	PAPER NUMBER
----------	--------------

1645

DATE MAILED: 11/03/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,604

Applicant(s)

BOLLEN ET AL.

Examiner

Tammy K. Field

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 30-78 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The Preliminary Amendment received June 20, 2001 has been entered in paper No. 6.

Claims 1-29 have been canceled and new Claims 30-78 are presently under examination.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 30-34, 47, 61-65, and 72-76 are drawn to the special technical feature of a 1st polypeptide product and kits thereof comprising a polypeptide, 1st method of making by a process for producing the polypeptide, and 1st method of using the polypeptide by a method of diagnosing a *Bordetella Pertussis* infection.

Group II, claim(s) 35-46, 48, 55-56, and 71 are drawn to the special technical feature of a polynucleotide and a kit thereof comprising a polynucleotide, 1st method of making by a process for expressing a polynucleotide, 1st method of using a polynucleotide by using a vaccine comprising a polynucleotide and *Bordetella Pertussis* antigen.

Group III, claim(s) 49-54, and 56 are drawn to a vaccine comprising a polypeptide and *Bordetella Pertussis* antigen (2nd method of using a polypeptide).

Group IV, claim(s) 57-70 are drawn to the special technical feature of an antibody and a therapeutic composition comprising an antibody immunospecific for a polypeptide, and 1st method of using an antibody by a method of diagnosing a *Bordetella Pertussis* infection.

Group V, claim(s) 77, is drawn to the special technical feature of a method of identifying virulence genes from a pathogenicity island containing a type III secretion system from pathogenic strains of bacteria.

Group VI, claim(s) 78, is drawn to the special technical feature of a method of determining whether a particular bacterial strain harbours a type III secretion system involved in pathogenicity.

3. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

An international and national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression of special technical features that define a contribution with each of the claimed inventions, considered as a whole makes over the prior art, see MPEP 1,475(a). There is no technical relationship required for Groups I, and II, IV, V, and VI. If multiple products, processes of manufacture or uses are claimed, the first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(a) and MPEP 1.476(c). Therefore, Group III is drawn to a 2nd method of using the claimed product. The inventions listed as Groups I-VI do not share a corresponding special technical feature under PCT Rule 13.2.

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Group I or Group III or Group IV

- A. SEQ ID NO: 42
- B. SEQ ID NO: 44
- C. SEQ ID NO: 46
- D. SEQ ID NO: 48
- E. SEQ ID NO: 50
- F. SEQ ID NO: 52
- G. SEQ ID NO: 54
- H. SEQ ID NO: 56
- I. SEQ ID NO: 58
- J. SEQ ID NO: 60
- K. SEQ ID NO: 62
- L. SEQ ID NO: 64
- M. SEQ ID NO: 66
- N. SEQ ID NO: 68
- O. SEQ ID NO: 70
- P. SEQ ID NO: 72

Group II

- Q. SEQ ID NO: 41
- R. SEQ ID NO: 43
- S. SEQ ID NO: 45
- T. SEQ ID NO: 47
- U. SEQ ID NO: 49
- V. SEQ ID NO: 51
- W. SEQ ID NO: 53
- X. SEQ ID NO: 55
- Y. SEQ ID NO: 57

Z. SEQ ID NO: 59
AA. SEQ ID NO: 61
BB. SEQ ID NO: 63
CC. SEQ ID NO: 65
DD. SEQ ID NO: 67
EE. SEQ ID NO: 69
FF. SEQ ID NO: 71

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. The claims are deemed to correspond to the species listed above in the following manner:

Group I, III, or IV – Claim 30, and Group II – Claim 35

The following claim(s) are generic: 30, 35, 49, 57, 77, and 78.

6. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Inventions of Group I, III, and IV, claim 30 drawn to polypeptide, vaccine comprising a polypeptide, antibody and a therapeutic composition comprising an antibody immunospecific for a polypeptide species and Invention of Group II, drawn to polynucleotide species lack a common core feature/structure and therefore fail to share a substantial technical feature disclosed as being essential to that utility. As such, each of the different technical features recited as Invention of Groups I-VI lack a corresponding technical feature and by definition do not meet the requirements of PCT Rule 13.2.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammy K. Field whose telephone number is (703) 305-4447.

The examiner can normally be reached on Monday-Friday from 7am-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909.

Papers relating to this application may be submitted to Technology Center 1600 Group 1640 by facsimile transmission. The faxing of such papers must conform to the notice published

Art Unit: 1645

in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

TF
Tammy K. Field
October 30, 2003

LJS
LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600